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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,710	10/03/2003	Arthur M. Krieg	C1039.70074US00	9983

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EXAMINER	
HORNING, MICHELLE S	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
04/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/679,710	KRIEG ET AL.	
	Examiner	Art Unit	
	MICHELLE HORNING	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *45-47 and 94-100* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45-47, 94-100* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is responsive to communication filed 2/4/2009.

Withdrawn Rejections

The following rejections have been withdrawn due to claim cancellation or amendments: Claim Objection (claim 52), 35 USC 102(b) (Yamamoto et al), and 35 USC 103 (Yamamoto et al, Tokunaga et al and Legendre and Szoka). Further, due to the abandonment of Application No. 10/928762, the double patenting rejection with respect to this abandoned application has been withdrawn.

Double Patenting-MAINTAINED

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 45-47 and 94-100 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over

claims 42, 44-53, 59, 64-69, 71-73 and 75-80 of copending Application No. 10/719493. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to the same method steps for stimulating an immune response, including administering a composition comprising a CG motif and an antigen.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 45-47 and 94-100 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 47-52 of copending Application No. 11/071,836. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to the same method steps for stimulating an immune response, including administering a composition comprising a TCG motif.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 45-47 and 94-100 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 42 and 44-48 of copending Application No. 11/503377. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to the same method steps for stimulating an immune response, including administering a composition comprising a TCG motif.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 45-47 and 94-100 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 28, 29 and 31 of copending Application No. 11/645106. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to the same method steps for stimulating an immune response, including administering a composition comprising a TCG motif.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Double Patenting-NEW

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 45 and 46 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 6, 7, 12, 16 and 17 of U.S. Patent No. 7488490. Although the conflicting claims are not identical, they are not patentably distinct from each other because sets of claims are methods comprising the same steps including administration of unmethylated CpG-containing sequences. Note that both sets claim structures of the same length as well as non-palindromic sequences. Additionally, they are both drawn to further administering antigens, including those derived from a virus, bacterium, fungus and a tumor.

Claim 45 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2 and 4 of U.S. Patent No. 7402572. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims are drawn to a method of administering sequences containing unmethylated CpG dinucleotides of the same length. Note that claim 4 is drawn to a species (GTCpGTT) and such a species anticipates a genius claimed by the instant application.

Claims 45 and 46 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-57 of U.S. Patent No. 6653292. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a method comprising the same steps, including administering unmethylated CpG sequences of the same length (more than 8 nucleotides) which are non-palindromic. The same results would be expected to occur by using the same steps. Further note that the claimed structures of

the '292 patent are drawn to a number of species and the species anticipate the genus of the instant application.

Claims 45 and 46 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 7223741. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '741 claims are drawn to CpG-containing compositions combined with antigens claimed in the instant application. Because the intended use of the product claimed in the '741 patent is to administer such immunostimulatory nucleic acids, this patent anticipates the methods of administration of the instant application.

Claims 45 and 46 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13 and 17-21 of U.S. Patent No. 6429199. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods comprising the same step of administering an unmethylated CpG sequence and an antigen.

Claims 45 and 46 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1, 4, 8, 9 and 10 of U.S. Patent No. 6406705. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '705 patent are drawn to a composition of an oligo comprising an unmethylated CpG and an antigen including those derived from a virus, bacterium, fungus and a tumor. Given the intended use of

such a composition is to be administered to a subject, the method claims of the instant application are anticipated.

Claims 45 and 46 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-49 of U.S. Patent No. 6239116. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods of administering an unmethylated CpG sequence that is non-palindromic. Note that the '116 patent is drawn to a number of species throughout the claims and such species anticipates the genus as claimed in the instant application.

Claims 45 and 46 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3-39 of U.S. Patent No. 6207646. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods comprising the same steps including administration of a non-palidromic CpG-containing sequence in combination with an antigen. Given the same steps would lead to the same results, the instant claims are anticipated. Note that the composition claims which include species of '646 are intended to be used for administration to a subject.

Conclusion

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELLE HORNING whose telephone number is

(571)272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. H./
Examiner, Art Unit 1648

/Gary B. Nickol /
Supervisory Patent Examiner, Art Unit 1646